510(k) Summary

In accordance with 21 CFR 807.92

K052478

SEP 2 8 2005

1. Date of preparation

September 06, 2005

2. Company information

BarcoView
35 President Kennedypark
B-8500 Kortrijk, Belgium
Tel. +32-(0)56-233-211
Fax +32-(0)56-233-457

3. Contact person

Lieven De Wandel
Official correspondent

4. Device information

- Trade name: MFCD 1219
- Common name: Medical flat panel display
- Classification name: System, Image Processing
- Classification number: 21 CFR 892.2050 / Procode 90LLZ

5. Predicate device

- Name: MFCD 2320
- 510(k) number: K040158
- Manufacturer: Barco NV

6. Device description

MFCD 1219 is a 19.0" color LCD display for medical viewing.

Niowatch is user-friendly software that allows to optimize the display for DICOM-compliant viewing.

7. Intended use

"The MFCD 1219 is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

8. Summary of technological characteristics

The device consists of two components:

- One 1.3-megapixel flat panel display
- NioWatch software

The flat panel display has a resolution of 1280 x 1024 pixels.

The NioWatch software allows to set the display function, display test patterns, calibrate the display and view additional display and display controller information.

Compared to the predicate device, MFCD 1219 has a different LCD panel with a somewhat smaller screen size and a lower resolution. The display has no built-in optical sensor and cannot be rotated into portrait orientation. The other components of the system are the same.

The device does not come into contact with the patient. It does not control any life sustaining devices either.

9. Conclusion:

The Barco MFCD 1219 is substantially equivalent to the predicate device, MFCD 2320.

The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and intended use.

Any difference between both devices does not affect safety or efficacy.

The 510(k) Pre-Market Notification for the Barco MFCD 1219 contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

510(k) Summary

In accordance with 21 CFR 807.92

1. Date of preparation

September 06, 2005

2. Company information

BarcoView
35 President Kennedypark
B-8500 Kortrijk, Belgium
Tel. +32-(0)56-233-211
Fax +32-(0)56-233-457

3. Contact person

Lieven De Wandel
Official correspondent

4. Device information

- Trade name: MFCD 1219 TS
- Common name: medical flat panel display
- Classification name: System, Image Processing
- Classification number: 21 CFR 892.2050 / Procode 90LLZ

5. Predicate device

- Name: MFCD 2320
- 510(k) number: K040158
- Manufacturer: Barco NV

6. Device description

MFCD 1219 TS is a 19.0" color LCD display for medical viewing, equipped with a 19.0" touchscreen panel.

Niowatch is user-friendly software that allows to optimize the display for DICOM-compliant viewing.

7. Intended use

"The MFCD 1219 TS is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

8. Summary of technological characteristics

The device consists of two components:

- One 1.3-megapixel flat panel display
- NioWatch software

The flat panel display has a resolution of 1280 x 1024 pixels.

The NioWatch software allows to set the display function, display test patterns, calibrate the display and view additional display and display controller information.

Compared to the predicate device, MFCD 1219 TS has a different LCD panel with a somewhat smaller screen size and a lower resolution. The display has no built-in optical sensor and cannot be rotated into portrait orientation. Additionally, the MFCD 1219 TS display is equipped with a 19.0" touchscreen panel. The other components of the system are the same

The device does not come into contact with the patient. It does not control any life sustaining devices either.

9. Conclusion:

The Barco MFCD 1219 TS is substantially equivalent to the predicate device, MFCD 2320.

The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and intended use.

Any difference between both devices does not affect safety or efficacy.

The 510(k) Pre-Market Notification for the Barco MFCD 1219 TS contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2005

Mr. Lieven De Wandel
Official Correspondent
Barco – Medical Imaging Systems
President Kennedypark 35
B-8500 Kortrijk
BELGIUM

Re: K052478
Trade/Device Name: MFCD 1219 and MFCD 1219 TS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 6, 2005
Received: September 12, 2005

Dear Mr. De Wandel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

.0(k) Number (if known): K052478

Device Name: MFCD 1219

Indications for Use:

"The MFCD 1219 is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

Prescription Use __XX___

(Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052478

INDICATIONS FOR USE

.0(k) Number (if known): K052478

Device Name: MFCD 1219 TS

Indications for Use:

"The MFCD 1219 TS is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

Prescription Use __XX___

(Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Hoffman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052478